

STATEMENT OF WORK
Veteran Affairs (VA) Western New York Upstate Healthcare System (WNYHS)
Compound Pharmacy
May 3, 2017

1. The Department of Veterans Affairs (VA) Veterans Integrated Service Network (VISN) 2, Western New York Upstate Healthcare System (WNYHS), Buffalo VA Medical Center (VAMC) has an ongoing program to furnish sterile compounding for commonly compounded pharmaceuticals for injection to those Veterans that require them and are eligible for assistance. It's VA's intention to solicit proposals in accordance with all terms, conditions, provisions, specifications, and schedules of this solicitation, and award a single contract on a competitive basis for VISN 2. Contract manager on the account must be available within 24 hours to all VISN 2 locations.
2. WNYHS anticipates accomplishing an Indefinite Delivery/Indefinite Quantity (ID/IQ) requirements contract on a firm fixed unit price basis from this solicitation. Award will be made on a Best Value basis.
3. This solicitation is intended for the Veterans Affairs (VA) Veterans Integrated Service Network (VISN) 2, Western New York Upstate Healthcare System (WNYHS) Buffalo VAMC:
VAMC Buffalo
3495 Bailey Avenue
Buffalo, NY 14215

4. DESCRIPTION OF SERVICE

- a. VA Sterile compounding regulations require any contracted sterile compounding facility to be an FDA registered outsourcing facility in accordance with the [FDA Compounding Quality act Title I section 503B](#). (Documentation must be provided)
 1. Compliance with current good manufacturing practices (CGMP)
 2. Labeling with adequate directions for use (section 502(f)(1))
 3. FDA approval prior to marketing (section 505)
- b. Must provide documentation of a successful FDA inspection within the last calendar year of the date the contract is awarded
- c. Stability data of compound substance must provide for the amount of days stated in section e below with industry standard of the compound substances stored at room temperatures..
- d. For any of the products that require a Patient Controlled Analgesia (PCA) syringe, the preferred brand of syringe is Becton Dickinson (BD). In the event BD brand is unavailable, Monoject and Terumo brand syringes are acceptable alternatives.
- e. Specific product requirements and estimated usage. The list below represents the high volume product requirements, and monthly as well as annual usage estimates.

Item Description	Case Quantity	Expiration Date	Monthly usage (cases)	Estimated Annual Usage (cases)
Calcium Chloride 1 gram in NS 50mL Bag	24	90 days RT	<1	10
Ephedrine 5mg/mL 5mL syringe (any brand)	25	90 days RT	4	48
Fentanyl 10mcg/mL in NS 250mL Bag	5	90 days RT	10	120
Fentanyl 5mcg/mL Bupivacaine 0.1% in NS	5	90 days RT	12	144

50mL PCA syringe				
Hydromorphone 0.2mg/mL in NS 50mL PCA syringe	5	90 days RT	48	576
Hydromorphone 1mg/mL in NS 50mL PCA syringe	5	90 days RT	7	84
Ketamine 10mg/mL 2mL syringe (any brand)	5	90 days RT	1	20
Ketamine 10mg/mL 10mL syringe (any brand)	5	90 days RT	1	20
Methohexital 10mg/mL in SWFI (5mL syringe) (any brand)	25	42 days RT	<1	4
Methohexital 10mg/mL in SWFI (10mL syringe) (any brand)	25	42 days RT	<1	4
Morphine 1mg/mL in NS 50mL PCA syringe(*Monoject, BD, or Terumo)	5	90 days RT	4	48
Norepinephrine 4mg in D5W 250mL Bag	12	90 days RT	4	48
Phenylephrine 100mcg/mL in NS 5 mL syringe (any brand)	25	90 days RT	5	60
Methohexital 10mg/mL in SWFI (10mL syringe) (any brand)	25	42 days RT	30	13

* Preferred brand is BD for PCA syringes

5. VA ELECTRONIC RECORDS

- a. The contractor shall have Controlled Substance Ordering System (CSOS) capability and will be provided access through VA firewall for the sole purpose of verifying CSOS credentials. The contractor shall not have access to electronic medical record (Computerized Patient Record System-CPRS Graphical User Interface-GUI and Veterans Health Information Systems and Technology Architecture-VISTA). For this purpose the contractor shall have computer(s) with the following minimum attributes at the time of award
 1. Windows XP
 2. 128MB RAM
 3. DSL Broadband Cable

6. DELIVERY/PERFORMANCE

- a. Requirements shall be delivered to the Buffalo VAMC within two (2) business days after receipt of the complete order/prescription, if order is placed prior to 2:30PM Eastern Standard Time (EST), at no additional charge. The Contractor shall notify the Facility COR in the event he/she is unable to deliver the required items in accordance with the Government's required delivery date.
- b. In the event the Government desires expedited delivery, the ordering activity shall telephonically contact the contractor and inquire into the feasibility of obtaining this condition. Orders/prescriptions that are requested to be expedited by the VAMC and mutually agreed upon, will be completed within 24 hours of agreement.
- c. Any additional costs incurred by the contractor for meeting this requirement shall be negotiated with the Contracting Officer in accordance with clause 52.212-4, Contract Terms and Conditions-Commercial Items.
- d. c. The Contractor shall be responsible for delivery of pharmaceuticals to the point of delivery specified in the contract. The contractor will pay and bear all charges to the specified point of delivery. The contractor will designate the mode of delivery carrier.
- e. a. Personnel assigned by the contractor to perform the services covered by this contract shall be qualified, competent professionals in accordance with the [FDA Compounding Quality act Title I section 503B](#). All work shall be performed by and under the supervision of a Pharmacist licensed in a State, Territory, or Commonwealth of the United States and meet the professional qualification criteria of VA in accordance with [VHA Handbook 5005/55 APPENDIX G15. LICENSED PHARMACIST QUALIFICATION STANDARD GS-660](#). Offers will be considered only from contractors

who are regularly established in the business and who in the judgment of the Contracting Officer, are financially responsible. The offeror shall have adequate, reliable competent staff to meet the requirement of this contract at all times throughout this contract. Contractor shall take swift corrective action regarding reported behavior issues with their employees. VA will not tolerate any disrespectful behavior/attitude towards its Veteran beneficiaries or VA staff.

- f. The Contracting Officer and COTR shall be notified in writing (either electronically or by hard copy) after award a listing of the key personnel assigned at the main vendor location and shall provide certifications and curricula vitae, resumes, and/or other pertinent information on the qualifications of the Supervising Pharmacist.
- g. During the first ninety (90) days of performance, the Contractor shall make **NO** substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer, in writing, within 15 calendar days after the occurrence of any of these events and provide the information required by paragraph (c) below. After the initial 90-day period of the contract, the Contractor shall submit the information required by paragraph (c) to the Contracting Officer at least 15 days prior to making any permanent substitutions.
 - (1) The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes, and any additional information requested by the Contracting Officer. Proposed substitutes shall have comparable qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within 15 calendar days after receipt of all required information of the decision on the proposed substitutes.
- h. The Contractor must have the capability to receive orders via facsimile transmission or via secure computer transmission. Contractor must have e-mail capability for rapid communication with VA personnel.
- i. If for any reason the delivery time will exceed what is specified herein, the Contractor shall immediately notify the Contracting Officer's Representative (COR), and show cause in the event he is unable to deliver the required items in accordance with the Government's required delivery date. Failure by the contractor to provide a written notification within 48 hours as specified above constitutes receipt of an order.

7. RECALL

- a. The contractor shall immediately notify the Buffalo VAMC and contracting activities (the Contracting Officer, the COR and designated POC) in the event of a product recall, removal, required adjustment, or required modification that is suggested or mandated by the contractor, distributor, manufacturer, or any regulatory or official agency. The information that shall be included in this notification includes:
 - 1. A complete item description/identification
 - 2. Administrative identification data including contract number, order numbers and order date
 - 3. Reasons for recall, removal, adjustment, or modification
 - 4. Instructions for appropriate corrective action.
- b. A waiver/exception to the product service delivery requirements stated above may be granted on a case by case basis by the facility COR in the event that it is determined these requirements would create an undue burden.

8. CONTRACTOR PERSONNEL SECURITY REQUIREMENTS

- a. All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Office of Security and Law Enforcement prior to contract performance. This requirement is applicable to all subcontractor personnel requiring the same access. If the investigation is not completed prior to the start date of the contract, the contractor shall be responsible for the actions of those individuals they provide to perform work for VA.
 - 1. Position Sensitivity -The position sensitivity has been designated as Low Risk
 - 2. Background Investigation -The level of background investigation commensurate with the required level of access is National Agency Check with Written Inquiries.
- b. Contractor Responsibilities

1. The contractor shall prescreen all personnel requiring access to the computer systems to ensure they maintain a U.S. citizenship and are able to read, write, speak and understand the English language.
2. The contractor shall submit or have their employees submit the following required forms to the VA Office of Security and Law Enforcement within 30 days of receipt:
 - i. Standard Form 8SP, Questionnaire for Public Trust Positions
 - ii. Standard Form 8SP-S, Supplemental Questionnaire for Selected Positions
 - iii. FD 258, U.S. Department of Justice Fingerprint Applicant Chart
 - iv. VA Form 0710, Authority for Release of Information Form
 - v. Optional Form 306, Declaration for Federal Employment
 - vi. Optional Form 612, Optional Application for Federal Employment
3. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract.
4. Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.

9. METHOD OF PAYMENT

- a. The Government's method of payment is the Government purchase card administered through US Bank. The contractor shall be able to participate and accept the Government card. Contractor will use Level II access, which will enable the Contractor the ability to enter the Purchase Order Number to US Bank when sending the transactions. However, payment will be made at the time the contractor delivers the compounded medication and upon receipt of an invoice for the services furnished
- b. Invoices shall be submitted electronically daily or at time of charge to designated VA facility for services rendered. This will ensure rapid validation and reconciliation of charges. Invoices shall include the contract number, purchase/delivery order number, date of performance, an itemization of services rendered for each item.
- c. Contractor is not authorized to receive payment until proof of delivery. No payment to the contractor is to be made until the contractor provides proof of delivery and/or copy of a shipping receipt.